

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kerry Zang et al.
Serial No.: 10/777,514
Filing Date: February 11, 2004
Confirmation No.: 5263
Group Art Unit: 3738
Examiner: Miller, Cheryl L.
Title: **CONICAL, THREADED SUBTALAR IMPLANT**

MAIL STOP AMENDMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION PURSUANT TO 37 C.F.R. § 1.131

I, the undersigned, hereby declare and state that:

1. I am over the age of 21 years, of sound mind, and competent in all respects to make this Declaration.
2. I am a coinventor of the subject matter of the above-referenced patent application, entitled *Conical, Threaded Subtalar Implant*, filed on February 11, 2004 (the "Application").
3. Prior to February 10, 2004, I gained a full understanding of the subject matter of at least the current version of Claims 40 and 55 of the Application (the "Invention"), as provided to me in a draft amendment by Baker Botts, L.L.P., the draft amendment attached hereto as Appendix A; therefore, I conceived the subject matter of the Invention prior to February 10, 2004.

4. Beginning after conception of the Invention, I participated in the design and manufacture of an apparatus that incorporated the subject matter of the Invention (the "Apparatus") and that was complete prior to February 10, 2004; therefore, I reduced the subject matter of the Invention to practice prior to February 10, 2004.

5. All of the work in conceiving and reducing the Invention to practice occurred in the United States.

6. Attached as Exhibit B are two excerpts from one drawing that was created prior to February 10, 2004. The excerpts, portions of which have been redacted for privacy reasons, are provided as evidence that the Apparatus was reduced to practice prior to February 10, 2004. The excerpts that are attached as Exhibit B illustrate the subject matter included in at least the current version of Claims 40 and 55.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. Further, I declare that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

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Declaration pursuant to 37 C.F.R. § 1.131 in regard to 10/777,514.

Signed this 30th day of March, 2007.


Shaher A. Ahmad

EXHIBIT A
DRAFT AMENDMENT OF THE CLAIMS

Claims 1-39 (**Cancelled**)

40. (New) A medical implant, comprising:

a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, the body having a length, the body being tapered along at least a majority of the length;

at least one continuous and uninterrupted thread formed around an exterior surface of the body and extending at least a majority of the length of the body, the at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone, the at least one thread being tapered with respect to a longitudinal axis of the body, the taper of the at least one thread being generally conical; and

a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch.

41. (New) The medical implant of Claim 40, wherein the taper of the body is substantially equal to the taper of the at least one thread.

42. (New) The medical implant of Claim 40, wherein a majority of the taper of the at least one thread is uniform.

43. (New) The medical implant of Claim 42, wherein the uniform taper of the at least one thread measures between 15 degrees and 20 degrees.

44. (New) The medical implant of Claim 42, wherein the uniform taper of the at least one thread measures approximately 18 degrees.

45. (New) The medical implant of Claim 43, further comprising an engagement formed in a trailing end of the body and adapted to receive a tool for rotating the implant about a longitudinal axis of the implant for implantation of the implant into the sinus tarsi.

46. (New) The medical implant of Claim 45, wherein the majority of the at least one thread further includes a crest width, wherein the ratio of the crest width to the thread height is at least 0.3.

47. (New) The medical implant of Claim 45, wherein the majority of the at least one thread further includes a crest width, wherein the ratio of the crest width to the pitch is at least 0.25.

48. (New) The medical implant of Claim 45, wherein the majority of the at least one thread further includes a crest width, wherein the ratio of the crest width to the pitch is between 0.25 and 0.4.

49. (New) The medical implant of Claim 45, wherein the majority of the at least one thread further includes a thread root width measuring between 0.020 inches and 0.040 inches.

50. (New) The medical implant of Claim 45, wherein the majority of the at least one thread further includes:

a thread angle measuring approximately 60 degrees;

a crest width, wherein the ratio of the crest width to the thread height is at least 0.3;

and

a thread root width measuring between 0.020 inches and 0.040 inches.

51. (New) The medical implant of Claim 50, wherein:

the uniform taper of the at least one thread measures approximately 18 degrees;

the thread height is approximately 0.032 inches;

the root width is approximately 0.030 inches; and

the pitch is approximately 0.090 inches.

52. (New) The medical implant of Claim 50, wherein:

the uniform taper of the at least one thread measures 18 degrees;

the thread height is 0.032 inches;

the root width is 0.030 inches; and
the pitch is 0.090 inches.

53. (New) The medical implant of Claim 50, wherein:
the uniform taper of the at least one thread measures approximately 18 degrees;
the thread height is approximately 0.041 inches;
the root width is approximately 0.030 inches; and
the pitch is approximately 0.100 inches.

54. (New) The medical implant of Claim 50, wherein:
the uniform taper of the at least one thread measures 18 degrees;
the thread height is 0.041 inches;
the root width is 0.030 inches; and
the pitch is 0.100 inches.

55. (New) A method of forming a medical implant, comprising:

providing a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, the body having a length, the body being tapered along at least a majority of the length; and

forming at least one continuous and uninterrupted thread around an exterior surface of the body, the at least one thread extending at least a majority of the length of the body, the at least one thread being configured to at least partially prevent displacement of a talus without penetrating bone, the at least one thread being tapered with respect to a longitudinal axis of the body, the taper of the at least one thread being generally conical, a majority of the at least one thread having a substantially constant thread height and a substantially constant pitch.

56. (New) The method of Claim 55, wherein the taper of the body is substantially equal to the taper of the at least one thread.

57. (New) The method of Claim 55, wherein a majority of the taper of the at least one thread is uniform.

58. (New) The method of Claim 57, wherein the uniform taper of the at least one thread measures between 15 degrees and 20 degrees.

59. (New) The method of Claim 57, wherein the uniform taper of the at least one thread measures approximately 18 degrees.

60. (New) The method of Claim 58, further comprising forming an engagement in a trailing end of the body, the engagement being adapted to receive a tool for rotating the implant about a longitudinal axis of the implant for implantation of the implant into the sinus tarsi.

61. (New) The method of Claim 60, wherein the majority of the at least one thread further includes a crest width, wherein the ratio of the crest width to the thread height is at least 0.3.

62. (New) The method of Claim 60, wherein the majority of the at least one thread further includes a crest width, wherein the ratio of the crest width to the pitch is at least 0.25.

63. (New) The method of Claim 60, wherein the majority of the at least one thread further includes a crest width, wherein the ratio of the crest width to the pitch is between 0.25 and 0.4.

64. (New) The method of Claim 60, wherein the majority of the at least one thread further includes a thread root width measuring between 0.020 inches and 0.040 inches.

65. (New) The method of Claim 60, wherein the majority of the at least one thread further includes:

- a thread angle measuring approximately 60 degrees;
- a crest width, wherein the ratio of the crest width to the thread height is at least 0.3;

and

- a thread root width measuring between 0.020 inches and 0.040 inches.

66. (New) The method of Claim 65, wherein:

- the uniform taper of the at least one thread measures approximately 18 degrees;
- the thread height is approximately 0.032 inches;
- the root width is approximately 0.030 inches; and
- the pitch is approximately 0.090 inches.

67. (New) The method of Claim 65, wherein:

- the uniform taper of the at least one thread measures 18 degrees;
- the thread height is 0.032 inches;
- the root width is 0.030 inches; and
- the pitch is 0.090 inches.

68. (New) The method of Claim 65, wherein:

- the uniform taper of the at least one thread measures approximately 18 degrees;
- the thread height is approximately 0.041 inches;
- the root width is approximately 0.030 inches; and

the pitch is approximately 0.100 inches.

69. (New) The method of Claim 65, wherein:

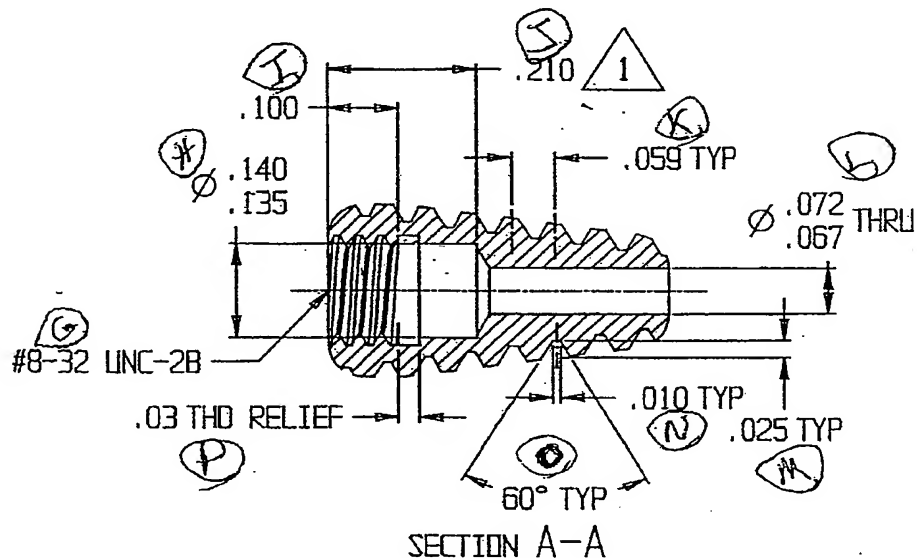
the uniform taper of the at least one thread measures 18 degrees;

the thread height is 0.041 inches;

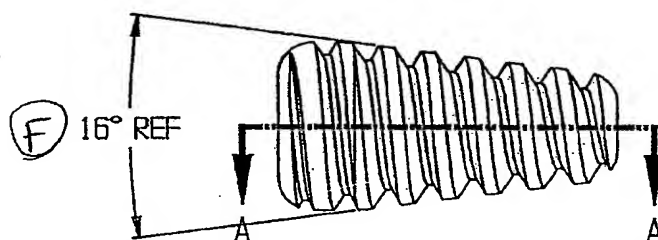
the root width is 0.030 inches; and

the pitch is 0.100 inches.

EXHIBIT B



min
min
Pilot



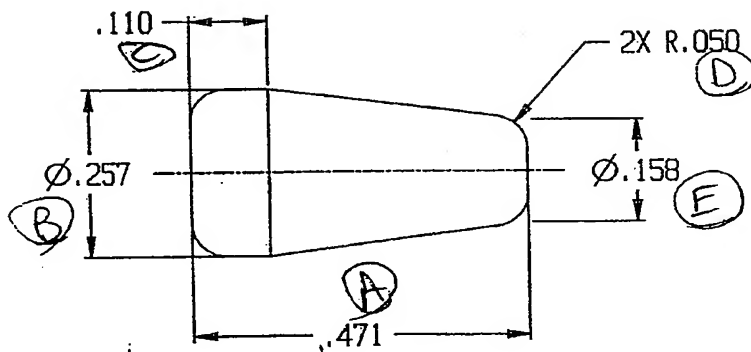
NOTES:


1. DRILL MINOR DIAMETER OF THREAD TO THIS DIMENSION
2. REMOVE ALL BURRS VISIBLE AT 20X MAGNIFICATION
3. CLEAN PER OPS-1003

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 .1300-.1389
 = #29, 136

REVISIONS			
LTR	DESCRIPTION	DATE	APPROVED
1	INITIAL RELEASE		



ALT. IND NO.	FIND NO.	QTY REQD	PART NUMBER	DESCRIPTION	MAT'L.
PARTS LIST					
UNLESS OTHERWISE SPECIFIED		SIGNATURES		DATES	
LINEAR DIMENSIONS ARE IN INCHES.		[REDACTED]		[REDACTED]	
TOLERANCES: .XXX = +/- .005		[REDACTED]		[REDACTED]	
.XX = +/- .01		[REDACTED]		[REDACTED]	
.X = +/- .1		[REDACTED]		[REDACTED]	
ANGLES: +/- 2 DEG.		[REDACTED]		[REDACTED]	
SURFACE FINISH 32		APPROVED		[REDACTED]	
MATERIAL Lot 031952 ACETAL COPOLYMER		[REDACTED]		[REDACTED]	
FINISH SEE NOTES		[REDACTED]		[REDACTED]	
 OSTEOMED L.P. ADDISON, TX 75001					
SUBTALAR TRIAL, SMALL					
SIZE B	FSCM NO.	DWG NO. 340-0013		REV 1	
SCALE 4:1	WT	REF	SHEET 1 OF 1		